LEGAL METROLOGICAL CONTROL OF BREATH ANALYZERS IN BRAZIL

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Abstract: In Brazil, the National Institute of Metrology, Standardization and Industrial Quality (Inmetro) is responsible for the metrological control of evidential breath analyzers, which is done by means of type approval as well as verification of these instruments. The requirements for these activities are documented in a Technical Metrological Regulation that was written based on the guidelines of Recommendation 126/1998 of the International Organization of Legal Metrology (OIML). In order to assure traceability, measurements are performed using certified reference material, which consists in gaseous mixtures of ethanol in nitrogen or liquid solutions of ethanol in water.

1. INTRODUCTION

Reduction of road traffic accidents is a key social goal for all governments. One way of achieving this objective is through strict oversight of drivers that are under the influence of alcohol.

Since 2008, Brazil has adopted a zero tolerance policy (prohibition) related to alcohol consuming, aiming at preventing transit injuries and fatalities [1].

Currently, one of the most known ways of examining drivers' sobriety is through the usage of evidential breath analyzers. Breath analysis has several advantages compared to blood analysis. Blood collection is invasive, requires medically trained personnel, analysis requires trained laboratory technicians, it is costly and the whole process takes time. The result of breath testing (measurement of the mass concentration of ethanol by analyzing deep lung air) is available rapidly and the cost is low.

Accuracy of breath analysis is critical to ensure the successful prosecution of the mentioned drivers in court. In Brazil, the National Institute of Metrology, Standardization and Industrial Quality (Inmetro) is responsible for the metrological control of evidential breath analyzers.

2. METHODOLOGY

Evidential breath analyzers (EBA) that are used by authorities as probative devices in traffic control are compulsorily submitted to strict metrological control. This control aims at providing the confidence level needed in the tests. Inmetro is the institution responsible for carrying out the activities of legal metrological control, in this case by means of type approval and verifications (initial and subsequent).

2.1. Type Approval

According to International Vocabulary of Terms in Legal Metrology (VIML) [2], type approval is a decision of legal relevance, based on the evaluation report, that the type of a measuringinstrument complies with the relevant statutory requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time.

In Brazil, the statutory requirements are documented on a Technical Metrological Regulation (RTM) [3], which was based on OIML R 126/1998 [4]. Among others, accuracy, repeatability, drift, memory effect, physical influence factors and durability tests are performed. Traceability is assured by using certified reference material, which consists in liquid solutions of ethanol in water. Certification of the mentioned reference material is provided by the Chemical Metrology Division of Inmetro. Gaseous mixtures of ethanol in nitrogen can also be used as far as it is verified that the EBA is also capable of measuring moist gases. Besides, the gaseous mixtures must be a certified reference material. When using gaseous mixtures, variations of atmospheric pressure have to be taken into account, as well as the quality of the containers (to minimize contamination and a possible change in composition of ethanol throughout its use cycle). When necessary, the correlation factor between the gaseous mixtures concentration and the result

showed by the EBA is provided by each manufacturer.

Only the breath analyzers that have their type approved can be used for evidential purposes in Brazil.

2.2. Initial Verification

Every new instrument must be submitted to initial verification before being sold to the final user, in order to assure that the device keeps the type approved characteristics. It is divided in two parts:

a. Examination for conformity with approved type (before tests): carried out to ascertain the EBA's conformity with the approved type. It is visually verified if the functions, mandatory information and position for verification and sealing marks are according to the type approved.

b. Accuracy and repeatability tests: Brazilian requirements for initial verification are stated on the same RTM used for type approval. The following requirements are applicable to individual measurements and not to any combination of measurements of a measuring cycle.

Accuracy – Tests are performed with whether liquid or gaseous reference material. The number of measurements on each mass concentration shall be:
Five, for 0.000 mg/L;
Ten, for the interval of 0.015 mg/L – 0.300 mg/L (excluding upper limit);
Ten, for the interval of 0.300 mg/L – 0.400 mg/L (excluding upper limit);
Ten for the interval of 0.400 mg/L up to the scale's upper limit.

Maximum permissible errors, positive or negative, on each indication shall be:
• 0.020 mg/L for all mass concentrations less than 0.400 mg/L;
• 5 % of the measured concentration for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L;
• 20 % of the measured concentration for all mass concentrations greater than 2.000 mg/L.

Repeatability - Standard deviation is estimated from the accuracy test data through the usage of equation 1:

$$s = \sqrt{\frac{\sum_{i=1}^{n}\left(Y_i - \overline{Y}\right)^2}{n-1}} \qquad (1)$$

where:
n = number of measurements made at a given mass concentration;
Y_i = the i[th] indication (out of n) of the EBA for that mass concentration;
$\overline{Y}$ = arithmetic mean of the n values.

Relative standard deviation is given by equation 2:

$$s_{relative} = \left(\frac{s}{\overline{Y}}\right) \times 100 \quad \% \qquad (2)$$

where:
s = standard deviation
$\overline{Y}$ = arithmetic mean of the n values.

The standard deviation for all mass concentrations less than 0.400 mg/L shall be less than 0.007 mg/Lx F_r.
The relative standard deviation for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L shall be less than 1.75 % x F_r.
The relative standard deviation for all mass concentrations greater than 2.000 mg/L shall be less than 6 % x F_r.

The statistical probability that the EBA satisfies the repeatability requirements is 95 % for each mass concentration. Considering chi-square distribution (χ^2), the required standard deviation values shall be expanded, which is done multiplying it by a rejection factor (F_r), obtained according to equation 3. See Table 1.

$$F_r = \sqrt{\frac{n-1}{q}} \qquad (3)$$

where:
n = number of measurements made at a given mass concentration;
q = constant obtained from χ2 distribution.

***Table 1** – q constants as a function of n for a probability of compliance of 95 % and the corresponding rejection factor (F_r).*

n	q	F_r
5	0.711	2.372
10	3.325	1.645

2.3. Subsequent Verifications

RTM demands that evidential breath analyzers be submitted to subsequent verifications (any verification after the initial one) at least every 12 months. However, the instrument owner can request verification at any time.

Accuracy and repeatability tests are performed as stated on the RTM and are showed below. The following requirements are applicable to individual measurements and not to any combination of measurements of a measuring cycle.

Accuracy – Tests are performed with whether liquid or gaseous reference material. The number of measurements on each mass concentration shall be:
Five, for 0.000 mg/L;
Ten, for the interval of 0.015 mg/L - 0.300 mg/L (excluding upper limit);
Ten, for the interval of 0.300 mg/L - 0.400 mg/L (excluding upper limit);
Ten for the interval of 0.400 mg/L up to the scale's upper limit.

Maximum permissible errors, positive or negative, on each indication shall be:
• 0.032 mg/L for all mass concentrations less than 0.400 mg/L;
• 8 % of the measured concentration for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L;
• 30 % of the measured concentration for all mass concentrations greater than 2.000 mg/L.

Repeatability - Standard deviation is estimated from the accuracy test data through the usage of equation 1.

The standard deviation for all mass concentrations less than 0.400 mg/L shall be less than 0.007 mg/Lx F_r.
The relative standard deviation for all mass concentrations greater than or equal to 0.400 mg/L and less than or equal to 2.000 mg/L shall be less than 1.75 % x F_r.
The relative standard deviation for all mass concentrations greater than 2.000 mg/L shall be less than 6 % x F_r.

Statistical probability that the EBA satisfies the repeatability requirements is 95 % for each mass concentration. Rejection factor (F_r) is obtained from equation 3.

Table 2 summarizes the requirements for each type of verification.

2.4. Documentation and Marking

a. Type Approval

Reports on examination and tests of the EBA carried out at pattern evaluation are filed. A document certifying that type approval has been granted is published on Official Union's Paper.

b. Initial and Subsequent Verification

Test report and examination report (only initial verification) of the EBA carried out at verification are filed.

A verification certificate is issued for each instrument, in case of a satisfactory result. This certificate contains the verification's expiring date and should be kept with the EBA. Also, the verification mark is fixed on the instrument as well as the sealing mark.

In case the instrument does not present satisfactory results, a rejection notice is issued, stating that the measuring instrument was found not to comply with the relevant statutory requirements. Besides, in the case of subsequent verification, the former verification mark is taken away.

3. RESULTS

Up to now, four different models of breath analyzers have their type approved in Brazil. Three of them are imported models and one is produced in Brazil. Details of the referred models can be seen on www.inmetro.gov.br .

***Table 2**. Requirements summary for initial verification and subsequent verification.*

Verification	n	Concentration (C)	Maximum permissible errors	Maximum permissible standard deviation
Initial	5	0.000 mg/L	0.020 mg/L	0.007 mg/L × F_r
	10	0.015 mg/L up to 0.300 mg/L (excluding the upper limit)		
	10	0.300 mg/L up to 0.400 mg/L (excluding the upper limit)		
	10	0.400 mg/L up to upper limit	5 % for 0.400mg/L ≤ C < 2.000 mg/L	1,75% × F_r for 0.400mg/L≤ C < 2.000 mg/L
			20 % for C > 2.000 mg/L	6 % × F_r for C > 2.000 mg/L
Subsequent	5	0.000 mg/L	0.032 mg/L	0.007 mg/L × F_r
	10	0.015 mg/L up to 0.300 mg/L (excluding the upper limit)		
	10	0.300 mg/L up to 0.400 mg/L (excluding the upper limit)		
	10	0.400 mg/L up to upper limit	8 % for 0.400mg/L ≤ C < 2.000 mg/L	1.75 % × F_r for 0.400mg/L≤ C < 2.000 mg/L
			30 % for C > 2.000 mg/L	6 % × F_r for C > 2.000 mg/L

In 2009, more than 9 thousand evidential breath analyzers were verified by Inmetro and by its state representative institutions.

Two months after adopting the zero tolerance policy (prohibition), Brazilian Highway Police estimates a reduction of 13.6 % on fatal accidents [5].

Also, in the state of Rio de Janeiro, from March, 2009 until January 1st 2010, about 3500 lives would have been saved [5].

4. CONCLUSIONS

Legal metrological control of evidential breath analyzers can help significantly in the reduction of accidents related to drunk driving by changing society's behavior.

Inmetro has been doing its duty of strengthening confidence in official measurements, carrying out type approval and verifications of evidential breath analyzers.

Public trust in reliable measurements encourages respect for traffic laws.

ACKNOWLEDGEMENTS

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